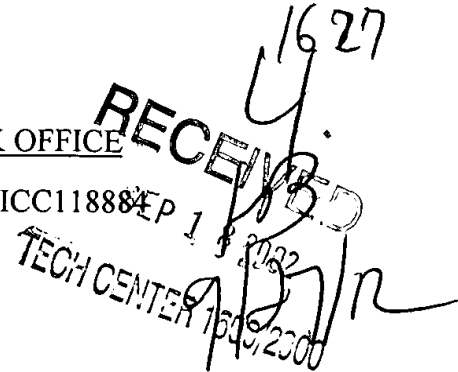


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: M.J. Corey et al. Attorney Docket No.: MICC118884P 1  
Application No.: 10/071,350 Group Art Unit: 1627  
Filed: February 8, 2002 Examiner: R.J. Gitomer  
Title: METHODS AND COMPOSITIONS FOR COUPLED  
LUMINESCENT ASSAYS



INFORMATION DISCLOSURE STATEMENT

TO THE COMMISSIONER FOR PATENTS:

Applicants are aware of the information listed in the attached form that may be material to the prosecution of the above-identified patent application.

1. X Copies of the listed patents, publications, and other information are enclosed for the Examiner's use.
2. X Pursuant to 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits.
3. X The Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this document is enclosed.

Respectfully submitted,

CHRISTENSEN O'CONNOR  
JOHNSON KINDNESS<sup>PLLC</sup>

  
Dennis K. Shelton

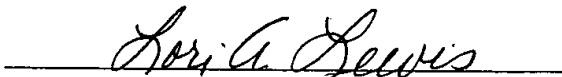
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Applicants: M.J. Corey et al. Attorney Docket No.: MICC118884

Application No.: 10/071,350 Group Art Unit: 1627

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Title: METHODS AND COMPOSITIONS FOR COUPLED  
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U.S. PATENT DOCUMENTS

None.

FOREIGN PATENT DOCUMENTS

*Examiner Cite	Kind	Publication Date	Country	English	Abstract	Translation
Initial No. Document No. Code (mm/dd/yyyy)				Provided	Provided	Provided
_____ F1	WO 98/28437	A1	07/02/1998	WIPO		
_____ F2	11-290096		10/26/1999	Japan	X	
_____ F3	WO 00/75167	A2	12/14/2000	WIPO		

OTHER INFORMATION

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Cite	
Initial No.	
_____ O1	Bradbury, D.A., et al., "Measurement of the ADP:ATP Ratio in Human Leukaemic Cell Lines Can Be Used as an Indicator of Cell Viability, Necrosis and Apoptosis," <i>Journal of Immunological Methods</i> 240:79-92, 2000.
_____ O2	Corey, M.J., et al., "A Very Sensitive Coupled Luminescent Assay for Cytotoxicity and Complement-Mediated Lysis," <i>Journal of Immunological Methods</i> 207:43-51, 1997.
_____ O3	Crouch, S.P.M., et al., "The Use of ATP Bioluminescence as a Measure of Cell Proliferation and Cytotoxicity," <i>Journal of Immunological Methods</i> 160:81-88, 1993.

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- O4 Kasatori, N., et al., "Cytotoxicity Test Based on Luminescent Assay of Alkaline Phosphatase Released From Target Cells," *Rinsho Byori* 42(10):1050-1054, October 1994, retrieved from *NCBI.gov*, <[http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\\_uids=7996714&dopt=Abstract](http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7996714&dopt=Abstract)> [retrieved August 2, 2002].
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- O11 Ximenes, V.F., et al., "Facile Chemiluminescent Method for Alkaline Phosphatase Determination," *Analytica Chimica Acta* 402:99-104, 1999.

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicants.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Camilla A. Santos, Jules S. Jacob, Benjamin A. Hertzog, Gerardo P. Casino,  
and Edith Mathiowitz

1616  
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Serial No.: 10/146,184

Art Unit: 1616

Filed: May 15, 2002

Examiner: Not Yet Assigned

For: *METHODS AND COMPOSITIONS FOR ENHANCING THE BIOADHESIVE  
PROPERTIES OF POLYMERS USING ORGANIC EXCIPIENTS*

Assistant Commissioner for Patents  
Washington, D.C. 20231

#### INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including five (5) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/729,529, filed December 4, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.



### U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
2,675,619	04-20-1954	Cone	33/76
2,677,700	05-04-1954	Jackson, et al.	260/488
2,979,578	04-11-1961	Curtis	200/32
3,036,118	05-22-1962	Jackson, et al.	260/484
3,535,307	10-20-1970	Moss, et al.	260/209
3,829,506	08-13-1974	Schmolka, et al.	260/615
4,757,128	07-12-1988	Domb, et al.	528/271
4,861,627	08-29-1989	Mathiowitz, et al.	427/213.31
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4,933,431	06-12-1990	Domb, et al.	528/271
4,938,763	07-03-1990	Dunn, et al.	604/891.1
4,976,968	12-11-1990	Steiner	424/491
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<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
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WO 91/06287	05-16-1991	Enzytech, Inc.	PCT
WO 92/11871	07-23-1992	Allergan, Inc.	PCT
WO 93/21906	11-11-1993	Brown University Research Foundation	PCT

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CHICKERING & MATHIOWITZ, "Bioadhesive microspheres: I. A novel electrobalance-based method to study adhesive interactions between individual microspheres and intestinal mucosa," *J. Control. Release* 34:251-62 (1995).

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EDELMAN, et al., "Perivascular and intravenous administration of basic fibroblast growth factor: Vascular and solid organ deposition," *Proc. Natl. Acad. Sci., USA* 90:1513-17 (1993).

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LI & LI, "Use of Enzymes in Elucidation of Structure", *The Glycoconjugates* (Horowitz, editor), pp. 51-67 (Academic Press 1977).

MATHIOWITZ, et al., "Novel microcapsules for delivery systems," *Reactive Polymers*, 6:275-83 (1987).

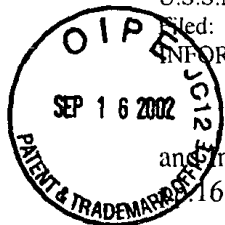
MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," *Scanning Microscopy*, 4(2):329-340 (1990)

MIKOS, et al., "Interaction of Polymer Microspheres with Mucin Gels as a Means of Characterizing Polymer Retention on Mucus," *J. Colloid & Interface Sci.*, 143(2):366-73 (1991).

U.S.S.N.: 10/146,184

Filed: May 15, 2002

INFORMATION DISCLOSURE STATEMENT



PARK, et al., "Alternative Approaches to Oral Controlled Drug Delivery: Bioadhesives and In-Situ Systems", Recent Advances in Drug Delivery Systems (Anderson & Kim, eds.) 163-83 (Plenum Press 1983?).

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U.S.S.N.: 10/146,184  
Filed: May 15, 2002  
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#### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patrea L. Pabst  
Reg. No. 31,284

Dated: September 13, 2002

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U.S.S.N.: 10/146,184  
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INFORMATION DISCLOSURE STATEMENT



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Erica C. Boughner

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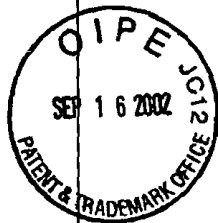
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/146,184
Filing Date	May 15, 2002
First Named Inventor	Camila A. Santos
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	BU 107 DIV CON CIP

Sheet 1 of 5

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document Number Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2,675,619	Cone	04-20-1954	
		2,677,700	Jackson, et al.	05-04-1954	
		2,979,578	Curtis	04-11-1961	
		3,036,118	Jackson, et al.	05-22-1962	
		3,535,307	Moss, et al.	10-20-1970	
		3,829,506	Schmolka, et al.	08-13-1974	
		4,757,128	Domb, et al.	07-12-1988	
		4,861,627	Mathiowitz, et al.	08-29-1989	
		4,898,734	Mathiowitz, et al.	02-06-1990	
		4,933,431	Domb, et al.	06-12-1990	
		4,938,763	Dunn, et al.	07-03-1990	
		4,976,968	Steiner	12-11-1990	
		4,997,904	Domb	03-05-1991	
		5,019,400	Gombotz, et al.	05-28-1991	
		5,173,298	Meadows	12-22-1992	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Office <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		EP 0 333 523	A2 UAB Research Foundation	09-20-1989		
		WO 91/06286	Enzytech, Inc.	05-16-1991		
		WO 91/06287	Enzytech, Inc.	05-16-1991		
		WO 92/11871	Allergan, Inc.	07-23-1992		
		WO 93/21906	Brown University Research Foundation	11-11-1993		

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Filing Date	May 15, 2002
First Named Inventor	Camila A. Santos
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	BU 107 DIV CON CIP

Sheet 3 of 5

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T <sup>2</sup>
		BECK, et al., "A new long-acting injectable microcapsule system for the administration of progesterone," <i>Fertil. &amp; Steril.</i> , 31(5):545-55 (1979).	
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		HARADA, et al., "Basic fibroblast growth factor improves myocardial function in chronically ischemic porcine hearts," <i>J. Clin. Invest.</i> , 94(2):623-30 (1994).	
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		LABAT-ROBERT & DECAEUS, "Glycoprotéines du mucus gastrique: structure, fonctions et pathologie," <i>Pathologie Biologie</i> , 24:241 (Paris 1979).	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number

10/146,184

Filing Date

May 15, 2002

First Named Inventor

Camila A. Santos

Group Art Unit

1616

Examiner Name

Attorney Docket Number

BU 107 DIV CON CIP

Sheet 4 of 5

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T <sup>2</sup>
		LABHASETWAR, et al., "Sotalol Controlled-release systems for arrhythmias: <i>In vitro</i> characterization, <i>in vivo</i> drug disposition, and electrophysiologic effects," <i>J. Pharm. Sci.</i> , <b>83</b> (2):156-164 (1994).	
		LEHR, et al., "Intestinal transit of bioadhesive microspheres in an <i>in situ</i> loop in the rat - a comparative study with copolymers and blends based on poly(acrylic acid)," <i>J. Controlled Rel.</i> , <b>13</b> :51-62 (1990).	
		LI & LI, "Use of Enzymes in Elucidation of Structure", <i>The Glycoconjugates</i> (Horowitz, editor), pp. 51-67 (Academic Press 1977).	
		MATHIOWITZ, et al., "Novel microcapsules for delivery systems," <i>Reactive Polymers</i> , <b>6</b> :275-83 (1987).	
		MATHIOWITZ, et al., "Morphology of polyanhydride microsphere delivery systems," <i>Scanning Microscopy</i> , <b>4</b> (2):329-340 (1990)	
		MIKOS, et al., "Interaction of Polymer Microspheres with Mucin Gels as a Means of Characterizing Polymer Retention on Mucus," <i>J. Colloid &amp; Interface Sci.</i> , <b>143</b> (2):366-73 (1991).	
		PARK, et al., "Alternative Approaches to Oral Controlled Drug Delivery: Bioadhesives and In-Situ Systems", <i>Recent Advances in Drug Delivery Systems</i> (Anderson & Kim, eds.) pp.163-83 (Plenum Press 1983?).	
		SMART, et al., "An <i>in vitro</i> investigation of mucosa-adhesive materials for use in controlled drug delivery," <i>J. Pharm. &amp; Pharmacol.</i> , <b>36</b> :295-99 (1984).	
		SPIRO, R., "Glycoproteins," <i>Annual Review of Biochemistry</i> , <b>39</b> :599-638 (Snell, ed. 1970).	

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Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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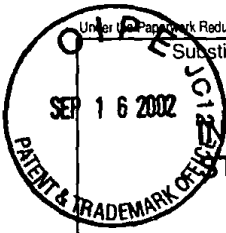
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

## Complete if Known

Application Number	10/146,184
Filing Date	May 15, 2002
First Named Inventor	Camila A. Santos
Group Art Unit	1616
Examiner Name	
Attorney Docket Number	BU 107 DIV CON CIP

Sheet 5 of 5

## OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T <sup>2</sup>
		TUTWILER, et al., "A Pharmacologic Profile of McN-3495 [N-(1-methyl-2-pyrrolidinylidene)-N-phenyl-1-pyrrolidinecarboxyimidamide], a New, Orally Effective Hypoglycemic Agent," <i>Diabetes</i> , <u>27</u> (8):856-67 (1978).	

Examiner's Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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Sheet	2	of	5
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## U.S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

[illegible]

Examine Signature		Date Considered	
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